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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,717	09/01/2000	Gabriel Villafane	EGYP 3.0-008	5779

530 7590 09/16/2003

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EXAMINER

COOK, REBECCA

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/653,717

Applicant(s)

VILLAFANE ET AL.

Examiner

Rebecca Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10,12-15,18,19,21-28,31-35,38,39,41,44-46 and 49-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10, 12-15, 18-19, 21-28, 31-35, 38-39, 41, 44-46, 49-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

Claims 15, and 18-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of nicotine or a derivative thereof for producing a drug for continuous administration of 0.2 mg to 5 mg per day per kilogram of body weight in a subject when being administered simultaneously with L-DOPA in a dose at least 30% lower than the effective dose when L-DOPA is administered alone, does not reasonably provide enablement for any and all doses of nicotine or L-DOPA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The nature of the instant invention is disclosed on page 4, lines 1-8. It is noted that applicants have amended independent claims 10, 28 and 53 to recite these limitations.

Claims 10, 12-14 and 53-54 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The word "progressive" in claims 10 and 55 is confusing and is not defined in the specification. It is noted that applicants have amended claims 44 and 50 to overcome this rejection.

In view of applicants' argument the rejection to claims 41 and 45 as containing new matter is withdrawn.

In view of applicants' amendments to claims 10, 28 and 53 their rejection under 35 USC 112, paragraph one to enablement is withdrawn.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 12, 15, 18-19, 22-28, 33-35, 38-39, 41, 44-46, 49-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Domino et al or applicants' admissions.

Domino (abstract, among others) discloses that nicotine and its derivatives, L-DOPA methyl ester and dopaminergic agonists are useful, alone and in combination, to treat neurodegenerative disease. Applicants admit (pages 2-3) that the current standard treatment of Parkinson's disease combines L-DOPA and D-2 receptor agonists. The instant claims differ over Domino and applicants' admissions in reciting specific combinations of the active compounds, method of titrating dosage, forms of administration, routes of administration and dosage amounts.

However, in the absence of a showing of unexpected results commensurate in scope with the claims, no unobviousness is seen in combining two or three compounds, each of which is known to be useful to treat the same condition, to form a composition or use in a method to treat the condition for which they are taught to be useful in the art, especially since Domino discloses that they are given in combination.

Applicants' argument that Domino does not suggest combining nicotine or a nicotine derivative with L-DOPA and a dopaminergic agonist is not persuasive. It would be obvious to one of ordinary skill in the art to combine the three compounds, each of which is taught in the art to be useful to treat the same condition.

Applicants' argument that the amounts in the instant invention are not taught by Domino is not persuasive. In the absence of a showing of unexpected results, once a method of using a composition is known it is within the skill of the artisan to determine the optimum amounts. Furthermore, once a composition and method of use are known in the art it is within the skill of the artisan to determine specific combinations of the active compounds, method of titrating dosage, forms of administration, routes of administration and dosage amounts.

Claims 13, 21, 31-32 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Domino et al or applicants' admissions as applied to claims 10, 12, 15, 18-19, 22-28, 33-35, 38-39, 41, 44-46, 49-53 above, and further in view of MEDLINE AN 86017126 (Lieberman).

Claims 13, 21, 31 and 54 further differ over Domino and applicants' admission in reciting a specific dopaminergic agonist. However, Lieberman discloses that bromocriptine, a dopaminergic agonist, improves the functionality of dopaminergic receptors and is used to treat Parkinson's disease. In the absence of a showing of unexpected results, it would be obvious to one of ordinary skill in the art to use bromocriptine in a composition comprising nicotine and its derivatives, L-DOPA and dopaminergic agonists, since Domino discloses that dopaminergic agonists are useful

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to treat Parkinson's disease and Lieberman discloses that bromocriptine is a dopaminergic agonist useful to treat Parkinson's disease.


Claim 32 differs over Domino and Lieberman in reciting that the treatment act on specific receptors in the brain. However, this describes the mechanism of action by which the compounds act to improve the functionality of dopaminergic receptors in the treatment of Parkinson's disease and does not impart patentability to the method for treating a neurodegenerative disease of claim 28.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
REBECCA COOK  
PRIMARY EXAMINER  
GROUP 1200 /614

September 15, 2003